

Remarks

Claims 9-27 are in this application. Claims 1-8 have been cancelled and replaced with new claims 12-19. Claims 12-19 are a rewriting of claims 1-8 from use claim format to method claim format. Claims 20-27 are also rewritten based on claims 1-8 and in claims 20-27, the method comprises administration of cardiotrophin-1 (CT-1).

The examiner requires that the claims in this application be restricted to one of the following groups:

I. Claims 1-10, drawn to “use” of a polynucleotide sequence encoding cardiotrophin-1 (CT-1) in the manufacture of a composition.

II. Claims 1-8, drawn to “use” of a cardiotrophin-1 polypeptide in the manufacture of a composition.

III. Claim 11, drawn to a method of cultivating hepatocytes comprising adding a viral vector bearing a polynucleotide sequence that expresses and codes for CT-1 to a medium and

IV. Claim 11, drawn to a method of cultivating hepatocytes comprising adding CT-1 polypeptide to a medium.

The restriction requirement is respectfully traversed.

It is submitted that at least the claims of groups I and II meet the unity requirements of PCT Rule 13.1. PCT Rule 13.2 sets out the test for unity of invention in cases arising under the PCT. The key test is whether there is “a technical relationship” among the subject matter of the claims involving the same special technical features, which are defined as those features which define the contribution which each of the claims makes over the prior art. In the present case, there is a

common inventive concept linking the subject matter of original claims 1-10, namely administration of cardiotrophin-1 (CT-1) or a polynucleotide that encodes CT-1. The effect of cardiotrophin-1, whether present prior to administration or after administration to a patient in, *inter alia*, stimulating hepatic regeneration and protecting hepatocytes is novel and inventive. The effect of cardiotrophin-1 on hepatocytes forms a common distinction over the prior art which applies to the subject matter of original claims 1-10, now claims 12-27.

It is noted that no lack of unity issue was raised in the International phase. Article 27 of the PCT requires that

No national law shall require compliance with requirements relating to the form and contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

This has been held in Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks, 231 USPQ 590 (E.D. VA 1986) to mean that the U.S. P.T.O. should, when considering issues of unity in applications which are national phase entries of International applications, apply the PCT's criteria for determining unity of invention. It is submitted that in applying this holding, the U.S.P.T.O. should give deference to the views of the International Preliminary Examination Authority (in this case the EPO) on the question of unity.

Therefore, it is respectfully requested that the claims of group I and II, namely, new claims 12-27 be examined in this application. If, the examiner does not agree that claims 12-27 should be examined in this application, a provisional election of the claims of Group II, now claims 20-27, is made.

This provisional election is made without prejudice to applicants' rights to pursue the other claims and/or other subject matter disclosed in this application in this application or in a further application.

Accordingly, it is submitted that this application is in condition for allowance.

Respectfully submitted,

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JANET I. CORD

LADAS & PARRY

26 WEST 61ST STREET

NEW YORK, NEW YORK 10023

REG. NO.33778 (212)708-1935